THE WEINBERG GROUP INC.

1220 Nineteenth St, NW, Suite 300
Washington, DC 20036-2400
Phone 202.833.8077
Fax 202.833.7057
e-mail science@weinberggroup.com

WASHINGTON
NEW YORK
SAN FRANCISCO
BRUSSELS
PARIS

VIA COURIER

June 9, 2005

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR §10.20 and §10.30, as provided for in 21 CFR §314.93 and Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act, to request the Commissioner of the Food and Drug Administration (FDA) to declare that the drug product Methylphenidate Hydrochloride Extended Release Tablets for oral administration in a 72 mg strength is suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Methylphenidate Hydrochloride Extended Release Tablets, 72 mg, is suitable for submission as an ANDA. The reference listed drug product upon which this petition is based is Concerta® (methylphenidate HCl) Extended-release tablets, approved in 18 mg, 27 mg, 36 mg and 54 mg dosage strengths, under New Drug Application (NDA) 21-121. This petition is submitted for a change in dosage strength from the reference drug product. Methylphenidate Hydrochloride Extended Release Tablets will be marketed as extended-release tablets in the dosage strength of 72 mg. The drug, the route of administration, and the recommendations for use are the same as those of the listed drug product. The proposed product would differ only in dosage strength from the Concerta® marketed product.

2005P-0257

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The proposed drug product is expected to demonstrate bioequivalence to the listed product; data will be submitted at a later date.

B. Statement of Grounds

The Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in dosage strength from that of a listed drug provided the FDA has approved a petition that proposed the filing of such an application. This petition requests a change in strength for the proposed drug from that of the reference listed drug.

According to the approved labeling for the reference listed drug product, Concerta® (methylphenidate HCl) Extended-release tablets, 18, 27, 36 and 54 mg, the starting dosage for patients who are not currently taking methylphenidate, or for patients who are on stimulants other than methylphenidate, is 18 mg once daily, not to exceed a maximum of 54 mg/day in children age 6 to 12 years of age. The approved labeling for Concerta® also provides dosing recommendations for the initial conversion of patients who are currently taking methylphenidate in twice-a-day or three-times-a-day immediate release doses of 10 mg to 45 mg/day, to doses of Concerta® from 36 to 54 mg/day, taken once daily in the AM. The approved labeling for Concerta® recommends that initial conversion should not exceed 54 mg/day, but that after conversion dosages may be adjusted to a maximum of 72 mg/day taken once daily in the morning.

The proposed package insert for the Methylphenidate Hydrochloride 72 mg Extended Release Tablets, will be consistent with the reference listed drug labeling. Also, the approved labeling for Concerta® includes dosing recommendations for the 72 mg/day doses. The labeling for the proposed strength of 72 mg will therefore be within the range of therapy allowed for in the approved label.

In summary, the proposed change in strength of Methylphenidate Hydrochloride Extended Release Tablets from that of the reference listed drug (i.e. a change from 18, 27, 36 and 54 mg to 72 mg) will not raise questions of safety or efficacy of the proposed product. The reference product labeling recommends a maximum of 72 mg/day in adolescents 13 to17 years of age. Currently this dosage strength is not available and can only be achieved by taking multiple doses of the 18 mg or the 36 mg Concerta® (methylphenidate HCl) Extended-release tablets. The proposed 72 mg Methylphenidate Hydrochloride Extended Release Tablets will offer the maximum dosage strength in one extended release tablet and will therefore provide patients and physicians greater ease in medicating at the 72 mg/day dose. The efficacy of the proposed 72 mg dosage strength is supported in the reference product labeling, where it recommends a maximum dose of 72 mg/day in adolescents 13 to 17 years of age. The approval of the proposed 72 mg strength

would therefore not present additional safety concerns because it is within the range of currently approved therapy.

The proposed product will differ from the listed drug only in dosage strength. The indications, route of administration, intended patient population, and recommendations for use will remain the same as for the Concerta® product. Therefore, there will be no difference in the safety and efficacy of the proposed strength of Methylphenidate Hydrochloride Extended Release Tablets.

The package insert for Concerta® is provided in Attachment 1 of this petition. The draft package insert for the proposed Methylphenidate Hydrochloride Extended Release 72 mg Tablets is provided in Attachment 2.

C. Pediatric Use Information

The Pediatric Research Equity Act, passed in December 2003, requires that applications submitted under section 505 of the Act, be evaluated for safety and efficacy in pediatric populations when the application is submitted for the following: A new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. The proposed petition seeks a change in dosage strength from that of the reference listed product, and therefore under the provisions of the Pediatric Research Equity Act, it is not necessary to evaluate the safety or efficacy in pediatric populations or seek a waiver or deferral for pediatric studies. Further support that this petition for a change in dosage strength is not subject to the Pediatric Research Equity Act was further clarified in a letter received from FDA (see Attachment 3). A letter from the Office of Generic Drugs received on December 18, 2003 in correspondence to a suitability petition submitted for a change in strength stated that, "under the Pediatric Research Equity Act, which was signed December 2003, it is not necessary to seek a waiver or deferral of pediatric studies for a change in strength".

The package insert of the listed drug, Concerta®, states that 72 mg/day dosing of methylphenidate hydrochloride is approved for use in adolescents 13 to 17 years of age, and that "Concerta®, should not be used in children under six years, since safety and efficacy in this age group have not been established". The proposed package insert for Methylphenidate Hydrochloride Extended Release Tablets, 72 mg will provide the same information for pediatric use as the reference product, Concerta®, and because the proposed change is a change in strength, no additional studies should be required.

D. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR §25.31.

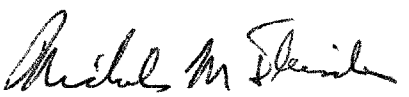
E. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

F. Certification

The undersigned certifies that to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,



Nicholas M. Fleischer, R.Ph., Ph.D.
Vice President – Clinical Pharmacology & Biopharmaceutics
THE WEINBERG GROUP INC.

NMF/kh

Enclosures

cc Gary Buehler, Director, Office of Generic Drugs (w/encls.)